

REMARKS

Claims 21-26 are pending in the present application. Applicant notes with appreciation that prior rejections under §102 were removed. In the Office Action mailed July 12, 2006, the Examiner maintained rejection of these claims under 35 U.S.C. § 103 as allegedly being unpatentable over Morecki in view of Kaminski and Gupta.

As noted by the Examiner, the instant claims are drawn to a method of administering a product. The Examiner asserts that the product used (*i.e.*, that is produced by the recited process steps) is identical to that disclosed by Morecki. Applicant respectfully disagrees.

Morecki teaches the administration of intact irradiated tumor cells. See, *e.g.*, the title of the Morecki reference ("*Induction of tumor immunity by intact irradiated leukemic B cells . . .*", and the Immunization Protocols recited in column 1 of page 237. As such, the product taught by Morecki necessarily includes all of the components of the tumor cells, not just immunoglobulin molecules associated with the tumor. Furthermore, the cells of Morecki are intact, so that any heavy chain variable regions included in the compositions are physically associated with a cell (*e.g.*, are within a cell, or are attached to the surface of a cell).

The product administered in the claimed method is distinct from Morecki because:

- a) The expressed product is "purified" from the expressing cell (see, *e.g.*, step vi) of Claim 21). As such, at least some fraction of the product is removed from association with an intact cell.
- b) The cells from which the product is derived are not the tumor cells of Morecki. The instant product is from a transformed cell that expresses at least two different recombinant heavy chain variable regions. It is well known in the art that mature B-cells, such as the intact tumor cells of Morecki, each express only a single immunoglobulin heavy chain. Thus, even if the purified product of the instant claims includes an intact transformed cell, the transformed cell is structurally distinct from the intact tumor cells of Morecki.
- c. The tumor cells used are not intact. The process of the instant claims comprises the step of isolating nucleic acid from malignant cells (*e.g.*, tumor cells). As such, the tumor cells used in the recited method are necessarily not intact. The teachings of Morecki, in which tumor cells are preserved intact, are directly

contrary to the instantly claimed method, which requires destruction of the recited tumor cells.

Regarding the use of the "comprising" language in the claims, the Examiner asserts that the composition of the instant claims encompasses more than the recited heavy chain variable regions, presumably referring to the additional cellular components in the intact cells of Morecki. Applicant respectfully points out that, even under the "comprising" language, the composition of the instant claim must include at least the recited purified multivalent preparation. Because Morecki teaches only intact cells, Morecki does not provide a product that comprises purified heavy chain variable regions, as required by the instant claims.


Applicant submits that the product used in the method of the instant claims is structurally distinct from the product disclosed by Morecki. The combination of Morecki with Kaminski and Gupta does not cure this deficiency and does not provide all of the elements of the instant claims. As explained in the Amendment and Response filed on April 12, 2006, and incorporated herein by reference, Kaminski provides the isolation of a single Id protein that is not "multivalent" in accordance with the present invention. In teaching the use of an isolated Id protein, Kaminski teaches away from Morecki's instruction to use intact tumor cells, and there is no motivation to combine these references. Furthermore, because Kaminski teaches the isolation of a single tumor Id protein, the process of Kaminski, even if applied to the tumor cells of Morecki, does not teach or suggest the purified multivalent composition produced by the process recited in the instant claims. Gupta teaches a variety of adjuvants and does not cure this deficiency.

For these reasons, Applicant respectfully asserts that the claims are not obvious in view of these references and Applicant respectfully requests that these rejections be removed.

CONCLUSION

For the reasons set forth above, it is respectfully submitted that all grounds for rejection have been addressed and should be removed, and that Applicant's claims should be passed to allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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